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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,995	03/23/2004	Marwan Abboud	21819-194U	2340

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Christopher & Weisberg, P.A.
200 East Las Olas Boulevard
Fort Lauderdale, FL 33324

EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	**PAPER NUMBER**
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,995	ABBOUD ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-11 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-11 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/09; 6/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and arguments, received April 20, 2009, have been fully considered by the examiner. In particular, the amendments and argument are deemed to overcome the 35 USC 112, first paragraph issues involving the particular pressure ranges to which the balloon is inflated and used for ablation. The following is a complete response to the April 20, 2009 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner maintains the specification fails to provide a disclosure of the steps being performed in accordance with an RF energy source as required by claim 10. While applicant's disclosure may suggest it is known to provide RF energy, there is no disclosure of the pressures associated with an RF embodiment.

Claim Rejections - 35 USC § 102

Claims 1-3, 9, 11 and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Joye et al (6,428,534).

Joye et al disclose a catheter device that is inflated and deflated within the cardiovascular system for performing cryogenic angioplasty. In particular, Joye et al disclose that it is advantageous to use lower balloon pressures (e.g. 2 bar, col. 8, lines 5-7) for ablating tissue with cryogenic cooling. In particular, Joye et al disclose various balloon inflation pressures and cycles, including flushing the balloon with a saline and dry gas (i.e. very low pressure), then pressurizing with a cryogen to treat the area (col. 9, lines 25-31). The pressure during the cryogen cycle, while still low, would be greater than the pressure in the balloon during the flushing cycle which is performed merely to remove fluids and debris before introducing the pressurized cryogen. Joye et al also disclose a pressure control feedback mechanism (col. 8, lines 5-20) which includes a control means on a console for controlling the necessary valves to regulate the delivery of cryogen from the cryogen source.

Claim Rejections - 35 USC § 103

Claims 4, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joye et al ('534) in view of the teaching of Edwards (6,258,087).

The Joye et al device and method of use has been addressed previously. While Joye et al disclose a controller to control the fluid delivery to maintain a desired pressure in the balloon, there is no specific teaching of using a PID controller. The examiner maintains that the use of PID controllers is generally known in the art, and

Edwards fairly teaches the use of such a controller to control fluid flow (col. 36, lines 15-20).

To have provided the Joye et al system with a PID controller to control the fluid flow based on sensed conditions such as pressure would have been an obvious consideration for one of ordinary skill in the art since Edwards teaches the use of such a control mechanism to control fluid delivery.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Joye et al ('534) in view of the teaching of Stern (5,443,470).

Joye et al disclose cryoablation as addressed previously, but fail to teach the alternative (or additional) use of RF energy.

Stern, as addressed in the previous Office action, disclose a balloon ablation apparatus that uses either RF energy or cryogenic energy to effect ablation of tissues with the balloon device.

Hence, to have provided the Joye et al system with an RF treatment means for ablating tissue would have been an obvious modification for one of ordinary skill in the art since Stern fairly teaches that it is known to use either RF energy or cryogenic energy to affect ablation of tissue with a balloon device.

Claims 3, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joye et al ('534) in view of the teaching of Joye et al (2002/0045894).

Joye et al disclose a system including a controller for controlling the inflation and deflation of the balloon, including controlling the pressure within the balloon. There is

no express depiction of a control console for performing this manipulation. The examiner maintains that as is generally known in all such systems, a control panel is present to afford the user access to control buttons. However, in order to more clearly show that such a control panel is known, attention is directed to the Joye et al ('894) references which specifically shows a control console (78) used for inflating and deflating a balloon (22). Joye et al further specifically teach of the use of a proportional valve (68) for maintaining a pressure in the balloon, as well as the use of a fixed volume reservoir (72) coupled to the proportional valve (68).

To have provided the Joye et al with a control console, proportional valve and a fixed volume reservoir to controlling the inflation/deflation and the pressure within a balloon structure would have been an obvious modification for one of ordinary skill in the art since Joye et al ('894) teach the use of such components in an analogous system for the same purpose.

Claims 1-3, 9, 11 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller (3,924,628) in view of the teaching of Joye et al ('534).

The Droegemueller device has been addressed previously. Droegemueller disclose the use of the device to treat uterine tissue, but specifically state that the device may be used in other treatment areas (col. 8, lines 5-10) with modification of the balloon shape/size. The examiner maintains that use of the device to treat blood vessels would be an obvious consideration since Joye et al fairly teach that it is known

to use cryo-balloon devices to treat blood vessels. Joye et al also specifically teach that it is known to use lower balloon pressures (e.g. about 2 bar) when using a cryo-balloon device, and Droegemueller also disclose the use of low balloon pressures. Joye et al further disclose the particular controller and sensors used to deliver fluids to the balloon member and to control the inflation pressure in the balloon.

To have used the Droegemueller balloon device to ablate tissue in the cardiovascular system would have been an obvious consideration for one of ordinary skill in the art, particularly since Droegemueller specifically disclose the device may be used in areas other than uterine tissue, and further since Joye et al teach that it is known to use cryo-ablation balloons having low inflation pressures to treat cardiovascular tissues.

Claims 4, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller ('628) and Joye et al ('534) and further in view of the teaching of Edwards (6,258,087).

The combination of the Joye et al teaching with the Droegemueller devices has been addressed previously. While Joye et al disclose a controller to control the fluid delivery to maintain a desired pressure in the balloon, there is no specific teaching of using a PID controller. The examiner maintains that the use of PID controllers is generally known in the art, and Edwards fairly teaches the use of such a controller to control fluid flow (col. 36, lines 15-20).

To have provided the Droegemueller device, as modified by the teaching of Joye et al, with a PID controller to control the fluid flow based on sensed conditions such as pressure would have been an obvious consideration for one of ordinary skill in the art since Edwards teaches the use of such a control mechanism to control fluid delivery.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Droegeumuller ('628) and Joye et al ('534) in view of the teaching of Stern (5,443,470).

Droegemueller and Joye et al disclose cryoablation as addressed previously, but fail to teach the alternative (or additional) use of RF energy.

Stern, as addressed in the previous Office action, disclose a balloon ablation apparatus that uses either RF energy or cryogenic energy to effect ablation of tissues with the balloon device.

Hence, to have provided the Droegemueller device, as modified by the Joye et al system, with an RF treatment means for ablating tissue would have been an obvious modification for one of ordinary skill in the art since Stern fairly teaches that it is known to use either RF energy or cryogenic energy to affect ablation of tissue with a balloon device.

Claims 3, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller ('628) and Joye et al ('534) and further in view of the teaching of Joye et al (2002/0045894).

Joye et al disclose a system including a controller for controlling the inflation and deflation of the balloon, including controlling the pressure within the balloon. There is

no express depiction of a control console for performing this manipulation. The examiner maintains that as is generally known in all such systems, a control panel is present to afford the user access to control buttons. However, in order to more clearly show that such a control panel is known, attention is directed to the Joye et al ('894) references which specifically shows a control console (78) used for inflating and deflating a balloon (22). Joye et al further specifically teach of the use of a proportional valve (68) for maintaining a pressure in the balloon, as well as the use of a fixed volume reservoir (72) coupled to the proportional valve (68).

To have provided the Droegemueller system, as modified by the teaching of the Joye et al, with a control console, proportional valve and a fixed volume reservoir to controlling the inflation/deflation and the pressure within a balloon structure would have been an obvious modification for one of ordinary skill in the art since Joye et al ('894) teach the use of such components in an analogous system for the same purpose.

Response to Arguments

Applicant's arguments filed April 20, 2009 have been fully considered but they are not persuasive.

Regarding the 35 USC 112, first paragraph rejection, applicant has indicated support for the claimed limitation at paragraph [0035] of the Published Application No. 2005/0215989. While the examiner agrees that this paragraph does recite a means to connect an RF energy source to the balloon device, there is no disclosure of providing the specific pressure ranges and sequences in a procedure utilizing RF energy as required by claim 10 (which depends from claim 1). That applicant has acknowledged

the potential use of RF energy in the cryocatheter device is not at point. However, applicant has disclosed numerous different embodiments, and numerous different control mechanisms to control an ablation procedure. There is no disclosure of using an RF energy source in a procedure which includes the pressure range and sequences as recited in the combined limitations of claims 1 and 10.

Regarding the Joye reference, applicant asserts that there is no disclosure in Joye of inflating an expandable member to a “predetermined target pressure" as required by claims 1 and 11. The examiner disagrees. It appears the difference of opinion is with respect to the scope of the claim language used in the claims. The examiner maintains that a “predetermined target pressure” is a very broad statement that could include any pressure for any point in time. Joye et al clearly provide a controller to control the inflation of the balloon as disclosed at column 8, lines 5-20. Applicant seems to be arguing that Joye fails to disclose selecting a target pressure prior to the procedure, inflating the balloon to that selected target pressure and maintaining that pressure for a selected time period (as is consistent with applicant's specification). However, the examiner asserts that this is a very specific definition for what is actually a much broader limitation. As addressed in previous Office actions, any pressure may be a "predetermined target pressure", including a pressure achieved as the balloon is inflated. For example, Joye clearly teach of providing a low pressure for flushing the balloon. A "low flushing pressure" may be deemed a "predetermined target pressure". There is no specific value or range associated with the limitation and it is entirely open to interpretation what would constitute a “predetermined target pressure”.

Moreover, even assuming Joye taught a specific range, for example 1 to 2 bars, for flushing the balloon, any pressure up to the maximum could be considered a "predetermined target pressure". There is no designation in the claim language that the “target pressure” has to be a maximum value that is applied, or that there is any time frame associated with a target pressure.

Similarly with respect to claim 2, there is no designation of what is meant by a predetermined temperature range. Moreover, Joye clearly discloses treating tissue to a desired temperature (i.e. "predetermined temperature range") as disclosed at column 3 of the patent. The examiner maintains this limitation is clearly met by the Joye reference.

Applicant’s arguments with respect to the remaining claims are based solely on the premise that the Joye reference fails to anticipate independent claims 1 and 11. The examiner maintains that the Joye reference continues to anticipate the claim language for the reasons expressed above, and that the obviousness rejections also remain tenable.

Regarding the combination of the Joye teaching with the Droegemueller reference, it is noted that Droegemueller disclose the use of the device to treat uterine tissue. However, as addressed in the rejection above (and in the previous Office action), Droegemueller also disclose alternative uses for the device. The examiner maintains that use of such a device in the cardiovascular system would be an obvious consideration in view of this disclosure of Droegemueller and further in view of the teaching of Joye. The Joye reference is deemed to fairly teach the steps of inflating to a

predetermined target temperature, and then exceeding the target temperature during ablation as argued above. As such, the examiner maintains that the combination of the Joye teaching with the Droegemueller device fairly meets the claimed limitations. Again, applicant has argued the dependent claims only to the extent that they are allowable for reasons expressed with respect to the independent claims. As the examiner maintains the position with respect to the independent claims, the dependent claims are deemed to also be properly rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
September 2, 2009